

REMARKS

Claims 1-58 are pending in the present application.

The rejection of Claims 1-23 under 35 U.S.C. §112, first paragraph (enablement), is obviated in part by amendment and traversed in part.

At the outset, Applicants thank Examiner Roberts for the recognition that the present application enables a method for “ameliorating, progress blocking and therapeutically treating one or more stress induced diseases.” (see page 3, lines 2-4 of Office Action mailed January 29, 2007). In view of this recognition, Claim 1 has been amended to be limited to this scope that the Examiner recognizes as being enabled.

With respect to preventing one or more stress induced diseases, Applicants have now presented this subject matter in new Claim 33 and the claims dependent therefrom. In this regard, the Examiner takes the position that, absent some definition in the specification, the term “prevention” equates to “100% success” or “complete eradication”. As such, any breakthrough instances of the disorder negate the ability to prevent (see Examiner’s analysis with anxiety bridging pages 5-6 of the Office Action). Further, the Examiner required evidence showing prevention throughout the full scope of the claimed disorders.

To this end, Applicants direct the Examiner’s attention to Examples 1-6 of the present application. In each of Examples 1-6, Applicants fed lysine-added diet prior to the various stresses loaded. The resulting data from Examples 1-6 clearly show that administering to a subject in need thereof an effective amount of a pharmaceutical composition comprising lysine prior to stressor introduction suppresses or prevents the instance of stress-induced diseases including anxiety disorders (see Example 1), irritable colon syndrome (see Example

2), gastric ulcer (see Examples 3 and 5), appetite loss (see Example 4), and anxiety and hypersensitivity (see Example 6).

Accordingly, the Examiner's comments bridging pages 3-7 of the Office Action are based on pure conjecture. In contrast, the present specification clearly and unequivocally demonstrates that the claimed method can prevent the recited disorders. Therefore, one of skill in the art would be able to practice the full scope of the presently claimed invention without undue experimentation.

Applicants request withdrawal of these grounds of rejection.

The rejections of: (a) Claims 1-11, 13, 15-20, and 22-23 under 35 U.S.C. §102(b) over Schaefer et al, (b) Claims 1-4, 13-17, and 20-21 under 35 U.S.C. §102(e) over Pitman, and (c) Claim 12 under 35 U.S.C. §103(a) over Schaefer et al, are obviated by amendment.

Schaefer et al disclose a method of treating antemortem stress for livestock. Also, in paragraph [0073] of Pitman subject #3 is described as having symptoms of memory loss and anxiety. The Examiner takes the position that giving "anxiety disorders" its broadest reasonable interpretation, this term in the originally claimed invention may read upon antemortem in Schaefer et al and anxiety in Pitman. Applicants direct the Examiner's attention to the definition of "anxiety disorders" of the present invention on page 3, line 9 and page 10, line 16. Specifically, in the present application "anxiety disorders" is defined as being "panic disorders and general anxiety disorders". The Examiner is reminded that "An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s)." MPEP §2111.01(IV). Thus, antemortem in Schaefer et al and anxiety in Pitman do not qualify in

the clinically recognized classes of individuals referred to by the term “anxiety disorders” in the present application.

Nonetheless, to ensure that neither Schaefer et al nor Pitman could even arguably read on the claimed invention, Claims 1 and 33 now define “anxiety disorders” with the following clause: “wherein said anxiety disorders is one or more of panic disorders and general anxiety disorders”. In view of the present amendment, neither Schaefer et al nor Pitman read on the claimed invention.

Withdrawal of these grounds of rejection is requested.

The rejection of Claims 1 and 21 under 35 U.S.C. §102(e) over Houston is obviated by amendment.

Claim 1 has been amended to recite the disorders of original Claim 15, which the Examiner recognizes as being free from the disclosure of Houston. Further, new Claim 33 also contains the language of original Claim 15.

Withdrawal of this ground of rejection is requested.

The rejection of Claims 1-14 and 16-23 under 35 U.S.C. §112, first paragraph (enablement), is obviated by amendment.

Claim 1 has been amended to recite the disorders of original Claim 15, which the Examiner recognizes as being enabled. Further, new Claim 33 also contains the language of original Claim 15.

Withdrawal of this ground of rejection is requested.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

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